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**NDSC Comments to the Centers for Medicare & Medicaid Services**

*Re: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer Disease*

CAG-00460N

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Submitted electronically via [www.cms.gov](http://www.cms.gov)

These comments are submitted on behalf of the National Down Syndrome Congress (NDSC). NDSC is the country's oldest national organization for people with Down syndrome, their families, and the professionals who work with them. We provide information, advocacy and support concerning all aspects of life for individuals with Down syndrome, and work to create a national climate in which all people will recognize and embrace the value and dignity of people with Down syndrome.

Down syndrome is the most frequently occurring chromosomal condition, affecting approximately 1 in 700 live births, and typically occurs when a person has three copies of chromosome 21 instead of two. Although exact numbers are still unknown, estimates have shown that there are at least 400,000 people with Down syndrome currently in the U.S. (but leading research organizations believe this number to be much higher.) Due to various factors over the past few decades such as advances in medicine, technology, deinstitutionalization, community integration and inclusive education, the lifespan for people with Down syndrome has increased from 25 years old in 1983 to approximately 60 years today. People with Down syndrome, who all experience a wide range of physical and cognitive delays, attend school, work, have meaningful relationships, and are productive and valued members of their communities.

Unfortunately, people with Down syndrome are at an increased risk of Alzheimer disease, which scientists believe results from the extra genes present on the 21<sup>st</sup> chromosome (which also carries a gene that produces amyloid precursor protein), as well as other factors such as accelerated aging of the brain. It is estimated that 50% of people with Down syndrome will develop dementia from Alzheimer disease as they age into their 40s and 50s, and that by age 65, this number will increase to 90%. This prevalence is astounding and horrifying and, without effective and affordable drugs, sentences most elderly people with Down syndrome to the ravages of this awful disease that will ultimately lead to their death.

CMS' proposed National Coverage Determination (NCD) would cover Food and Drug Administration (FDA) approved monoclonal antibodies that target amyloid for the treatment of Alzheimer disease through coverage with evidence development (CED), which means that FDA-approved drugs in this class would be covered for people with Medicare only if they are enrolled in qualifying clinical trials. The NCD specifically excludes coverage for patients who have "any neurological or other medical condition (other than AD) that may significantly contribute to cognitive decline." It appears that this exclusion would apply to 100% of people with Down syndrome. This exclusion does not apply to any single drug, but to an entire class of drugs now known or developed in the future. Since the vast majority of people with Down syndrome rely upon Medicare/Medicaid for health coverage and do not have secondary coverage, they would otherwise not be able to afford these potentially life-altering Alzheimer medications that CMS would cover for people without Down syndrome.

NDSC is not a research-based organization; our focus is on serving people with Down syndrome and their families to advocate for equal rights and opportunities and to improve their quality of life. We know discrimination when we see it. If CMS is going to cover Alzheimer treatments for any Medicare/Medicaid recipients, it must cover treatments for all of them without regard to disability status. Treatment decisions should be solely left up to the patient and their doctor and, if it is determined that a particular Alzheimer treatment could benefit a patient with Down syndrome, then that patient should have access to the covered treatment just as any other Medicare patient would. The proposed NCD by CMS is blatantly discriminatory against people with Down syndrome and will leave an entire generation of people with Down syndrome without any meaningful access to potentially lifesaving Alzheimer treatments. As a matter of health equity, we urge CMS to abandon the proposed CED process and instead adopt a non-discriminatory approach.

Thank you for the opportunity to comment on this process. For further information regarding these comments, please contact NDSC's Executive Director Jordan Kough at [jordan@ndscenter.org](mailto:jordan@ndscenter.org)